K120517

APR 26 2012

510(K) SUMMARY

Submitter:	Medos International Sàrl Chemin-Blanc 38 Le Locle, CH-NE 2400, Switzerland
Contact Person:	Eugene Bang Regulatory Affairs Associate DePuy Spine, Inc. Voice: (508) 977-3966 Fax: (508) 828-3797
Date Prepared:	February 17, 2012
Trade Name:	DePuy Pulse Cervical Cage System
Device Class:	Class II
Product Code(s):	ODP
Common Name:	Intervertebral Fusion Device with Bone Graft, Cervical
Classification Name:	Intervertebral Body Fusion Device
Regulation Number:	888.3080
Predicate Devices:	Bengal System – K081917, K103488 Concorde System – K081917 Lumbar I/F Cage System – P960025[1] LDR Spine Cervical Interbody Fusion System – K091088
Device Description:	The DePuy Pulse Cervical Cage System is designed for use as a cervical intervertebral body fusion device. The implant devices are available in various geometries and sizes to accommodate patient anatomy. The implant devices are manufactured from medical grade polyetheretherketone (PEEK OPTIMA® LT1) per ASTM F-2026 and also contain tantalum wires per ASTM F-560. The DePuy Pulse Cervical Cage System also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.

[1] This device was re-classified from a Class III (PMA) device to a Class II (510K) device via petition approved on 2007

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Indications: The DePuy Pulse Cervical Cage System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by patient history and radiographic studies) at one level of the cervical spine with accompanying radicular symptoms. Patients should have six weeks of non-operative treatment prior to surgery. The DePuy Pulse Cervical Cage System implants are used to facilitate fusion in the cervical spine (C2 – T1) and are placed via an anterior approach using autogenous bone. DePuy Pulse Cervical Cage System implants are intended to be used with supplemental internal fixation system.

Materials: Manufactured from medical grade polyetheretherketone (PEEK OPTIMA® LT1) per ASTMF F-2026 and tantalum wires per ASTM F-560.

Comparison to Predicate Device: The substantial equivalence of the subject device to the predicates indentified above is based upon the equivalence of intended use, design (fundamental scientific technology), materials, manufacturing methods, performance, sterility, biocompatibility, safety and packaging design.

Non-clinical Test Summary: The following mechanical tests were conducted:

- Static and dynamic compression testing in accordance with ASTM F-2077 Standard Test Method for Intervertebral Body Fusion Devices. The acceptance criteria was/were met.
- Static and dynamic torsion testing in accordance with ASTM F-2077 Standard Test Method for Intervertebral Body Fusion Devices. The acceptance criteria was/were met.
- Static and dynamic compression shear testing in accordance with ASTM F-2077 Standard Test Method for Intervertebral Body Fusion Devices. The acceptance criteria was/were met.
- Subsidence testing in accordance with ASTM F-2267 Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression. The acceptance criteria was/were met.

Clinical Test Summary: No clinical tests were performed.

Conclusion: Based on the predicate comparison and testing, the subject device DePuy Pulse Cervical Cage System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Raynham, Massachusetts 02767

APR 2 6 2012

Re: K120517
Trade/Device Name: DePuy Pulse Cervical Cage System
Regulation Number: 21 CFR 8880.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: February 17, 2012
Received: February 21, 2012

Dear Mr. Bang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K120517

Device Name: DePuy Pulse Cervical Cage System

Indications For Use:

The DePuy Pulse Cervical Cage System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by patient history and radiographic studies) at one level of the cervical spine with accompanying radicular symptoms. Patients should have six weeks of non-operative treatment prior to surgery. The DePuy Pulse Cervical Cage System implants are used to facilitate fusion in the cervical spine (C2 – T1) and are placed via an anterior approach using autogenous bone. DePuy Pulse Cervical Cage System implants are intended to be used with supplemental internal fixation system.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120517